



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,997	01/16/2004	Mark T. Marshall	P0020093.00/LG10126	8682
27581	7590	06/23/2011		
Medtronic, Inc. (CRDM) 710 MEDTRONIC PARKWAY NE MS: LC340 Legal Patents MINNEAPOLIS, MN 55432-9924			EXAMINER ALTER, ALYSSA MARGO	
			ART UNIT	PAPER NUMBER
			3762	
			NOTIFICATION DATE	DELIVERY MODE
			06/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.docketingus@medtronic.com

medtronic_crmd_docketing@cardinal-ip.com

Office Action Summary

Application No.

10/759,997

Applicant(s)

MARSHALL ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6 and 8-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6 and 8-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 25, 2011 has been entered.

Response to Arguments

2. Applicant's arguments filed April 25, 2011 have been fully considered but they are not persuasive. In response to applicant's argument that "if the coiled conductor 16 of Halperin were replaced by the cable of Anderson et al. the conductor 16 would not include a stylet receiving lumen and would, therefore, be unable to accept a stylet", the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

3. The examiner relies on Anderson et al. for the teachings of multiple wire strands disposed around multiple wire strands, and not the bodily incorporation of both structures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-6 and 8-34 stand and claims 35-40 are rejected under 35

U.S.C. 103(a) as obvious over Halperin et al. (US 5,564,434 A) in view of Anderson et al. (US 4,552,432). Halperin et al. discloses a lead body with a sensor module as seen in figures 2 and 3. *"The pressure sensor module 20 is located just proximal to the distal tip tine assembly 26 and is mechanically and electrically connected to the coaxial, outer and inner, coiled wire lead conductors 14 and 16"*(col. 7, lines 20-24). The two wire lead conductors, 14 and 16, are separated by an inner insulating sleeve 46 and encased by an outer insulating sleeve 46. Since coil 16 is disposed within coil 14, the examiner considers conductor 14 to be the coil conductor and coil 16 to be the cable conductor disposed within conductor 14. As seen in figure 3, the cable conductor is comprised two coiled wires. Halperin discloses inner and outer coils, 14 and 16 depicted in figure 3.

5. Halperin discloses the device substantially as claimed except for the conductor having an inner and outer coil created from a plurality of wire strands. Anderson et al. discloses a multilayered inner and outer coil comprised of multiple wire strands (see figure 1; col. 2, lines 8-25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cable coiling as disclosed by

Halperin et al. with the multilayered inner and outer multiple wire strand coils as disclosed by Anderson et al. in order to provide the predictable results of improving tensile strength, protecting the inner coil and stylet lumen as well as reducing the interference of the carried signals.

6. Additionally, the electrically insulative layer between the two conductors is the insulating sleeve 22 (Halperin, figure 3). Furthermore, since the insulative sleeve covers the cable conductor (coil 16), the examiner considers it to be a coating over cable conductor.

7. Alternatively, although the examiner considers the modified Halperin et al. to disclose an insulative coating above, it would have been obvious at the time the invention was made to substitute the insulative sleeve over the cable conductor with an insulative coating on the exterior in order to yield the predictable results of insulating the conductor and reducing the diameter of the lead.

8. Furthermore, Halperin et al. discloses the use of polyurethane insulation, which has a dielectric coefficient or dielectric constant less than 10. Since the coil 14 and the coil 16 are formed from two separate components, there is necessarily a gap between the two, since they are not unitary.

9. The modified Halperin et al. discloses the claimed invention except for the specific ranges of the size of the coil, insulation and the gap dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the size of the coil, insulation and the gap dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). Furthermore, determining the most appropriate size by routine experimentation would be prima facie obvious to one having ordinary skill in the art.

10. Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the size and dimension of the lead components as taught by the modified Halperin et al. with a specific range since it was known in the art that modifications to the size and dimension of lead components to create a larger or more compact lead, the would modify the lead to meet specific patient needs.

11. As to claims 3, 8-14, 22-29, the modified Halperin et al. discloses the claimed invention except for the preferred material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the the employed material as taught by Halperin et al. with the preferred material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07).

12. As to claims 35-36 and 38-39, the modified Halperin et al. discloses a cable conductor having an outer layer of a plurality of multilayered strands disposed around an inner layer of multiple wire strands. Since the inner layer of wire strands comprise a lumen to receive a stylet, the examiner considers the stylet to be a "center strand" wherein "the multiple strands of the inner layer are wound around the center strand".

Art Unit: 3762

13. As to claims 37 and 40, the modified Halperin et al. discloses the device substantially as claimed but does not explicitly mention "the outer diameter of the insulative layer is greater than 1.4 times the inner diameter of the insulative layer". It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the size and dimension of the insulative layer, since it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984.) See the MPEP 2144.04

14. Furthermore, such a modification would provide the predictable results of ensuring there is a sufficient insulative layer disposed between the cable conductor and the coil conductor to prevent the crossing of electrical signals.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alyssa M Alter/
Examiner
Art Unit 3762